APPELLANTS' BRIEF ON APPEAL
UNDER 37 C.F.R. § 1.192
U.S. Appln. No. 09/717,088

I. REAL PARTY IN INTEREST

The real party of interest is assignee EVER POWER HOLDING, INC. by virtue of an assignment executed by the Appellant.

I. RELATED APPEALS AND INTERFERENCES

To the best of the knowledge and belief of the Appellant, the assignee and the undersigned, there are no other appeals or interferences before the Board of Appeals and Interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

II. STATUS OF CLAIMS

Claims 1-22 have been cancelled. Claims 23-38 are pending.

This is an appeal from the Final Rejection dated April 9, 2003, of the Primary Examiner Gina C. Yu, Art Unit 1617, maintaining the rejection under 35 U.S.C § 103 of pending Claims 22-38.

III. STATUS OF AMENDMENTS

No amendments to the claims were filed after the Final Rejection dated April 9, 2003.

IV. SUMMARY OF THE INVENTION

Appellant's invention relates to a non-aerosol sprayable skin patch/bandage composition which advantageously avoids the problems associated with using propellants, such as discomfort, and is advantageous in the prevention or treatment of local or topical disease states or conditions of the skin as it allows

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Thomas S.Y. KO Conf. No.: **1770**

Appln. No.: **09/717,088** Group Art Unit: **1617**

Filed: **November 22, 2000** Examiner: **Yu, G.**

For: **NOVEL COMPOSITIONS AND METHODS**

APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. § 1.192

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 1.192, Appellants submit the following:

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Thomas S.Y. KO Conf. No.: **1770**

Appln. No.: **09/717,088** Group Art Unit: **1617**

Filed: **November 22, 2000** Examiner: **Yu, G.**

For: **NOVEL COMPOSITIONS AND METHODS**

SUBMISSION OF APPELLANT'S BRIEF ON APPEAL

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an original and two copies of Appellant's Brief on Appeal. A check for the statutory fee of $165.00 (small entity status) is attached. The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

Gordon Kit
Registration No. 30,764

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: May 10, 2004

gases and water through the patch to thereby reduce irritation to the skin, whilst simultaneously providing an effective delivery of the therapeutic component. Additionally growth of micro-organisms beneath the patch may be minimized with the present invention, and further the present invention provides for predeterminable patch degradation (see page 16, lines 20-35; page 17, lines 5-8; and page 24, line 5 to page 25, line 16 of the present specification).

Thus, the present invention provides a non-aerosol sprayable skin patch composition which consists essentially of:

(a) 0.01% to 10% w/w of at least one water-soluble physiologically active ingredient;

(b) 1% to 50% w/w of at least one substantially water insoluble film forming agent selected from the group consisting of acrylic acid, polyacrylic acid, polybutylmethacrylate, polymethacrylic acid, ascorbyl palmitate, carbomer, cellulose acetate phthalate, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, ethyl cellulose, hydroxpropyl methlycellulose phthalate, hypomellose phthalate, crospovidone, cetyl alcohol, poloaxmer, polyethylene glycol, polyvinyl acetate, polyvinyl acetate phthalate, polyvinyl alcohol, and povidone;

(c) 0.1% to 20% w/w of at least one film plasticizer agent; and

(d) 30% to 90% w/w of at least one volatile organic solvent,

wherein said composition forms a flexible porous and physiological compatible skin bandage when sprayed onto skin and

allowed to dry, wherein said bandage disintegrates progressively over a 24-48 hour time period (Claim 22 and see page 4, lines 2 and 22; page 16, lines 29-35; and page 18, lines 30-34 of the present specification).

In addition to the above, the Appellant's invention relates to a method of improving wound healing or administering a physiologically active ingredient, and methods of treating skin wounds, fungus infections, eczema and other skin conditions (see page 4, lines 24-31 and the Examples at pages 19-30 of the present specification).

V. ISSUES

At issue is the finding of the Examiner that Claims 22-38 are not patentable under 35 U.S.C. § 103 over U.S. Patent 3,987,000 (Gleichenhagen et al) in view of U.S. Patent 5,632,727 (Tipton et al) and/or U.S. Patent 708,023 Modak et al.

VI. GROUPING OF CLAIMS

The claims do not stand or fall together.

VII. ARGUMENT

A. Introduction

The claims on appeal are Claims 22-38. The generic independent composition claim is Claim 22. Composition Claims 23-34 depend either directly or indirectly on Claim 22. Method Claims 37 and 38 depend directly on Claim 22.

Composition Claim 35 is independent and Claim 36 depends thereon.

B. The Examiner's 35 U.S.C. §103 Rejection is Improper

1. Gleichenhagen et al

Gleichenhagen et al is a reference over 25 years old. Gleichenhagen et al describes a film forming polymer composition, especially of the type that can be sprayed from aerosol containers. The polymer must form a thin tough flexible elastic film on the skin, which adapts to skin movements without tearing.

The film forming sprayable solution of Gleichenhagen et al comprises a solution of a co-polymer including isobutene, a monomer of one or more esters of acrylic or methacrylic acid, and a monomer of one or more maleic acid monoalkyl esters. These co-polymers are dissolved in a volatile organic solvent.

Gleichenhagen et al discloses, at column 3, lines 17-22, that the prior art polymers produce:

> ...brittle, easy torn films and must be plasticized for the anticipated purpose by adding softening agents. Thus a danger exists that these softening agents may be partially absorbed by the skin in addition to having possible irritating effect. This is not an inconsiderable factor from a toxicological point of view.

Gleichenhagen et al, at column 3, lines 49-52, goes on to say in respect to the invention described therein:

> In particular, the film-forming substance should meet the necessary requirements without addition of auxiliary agents, such as softening agents. (Emphasis added)

In the Advisory Action dated November 7, 2003, at page 2, first full paragraph the Examiner states:

> Gleichenhagen cannot be categorized as teaching that all previously known film forming polymers that were well known and conventionally used in sprayable bandage compositions art somehow have defects.

The Examiner's position is also found in the Final Rejection dated April 29, 2003, at page 3, first paragraph thereof:

> Thus applicants' suggestion that the Gleichenhagen reference somehow teaches disadvantages of using conventional film-forming polymers for wound-bandage sprayable solution is unpersuasive.

Appellant's respectfully submit that Gleichenhagen et al is an invention which is plainly stated to address the problems of the prior art. It is a specific copolymer system. Thus, it is believed the Examiner's position on the teachings of Gleichenhagen et al is improper. It is a very different composition from Appellant's invention.

The advantages of Gleichenhagen et al are based on, in part, the fact that the co-polymer has particles of desired properties and does <u>not</u> require the presence of plasticizers/softening agents to give the required flexibility etc. Therefore, one of the characteristics of the invention of Gleichenhagen et al can be said to be the <u>absence</u> of plasticizers.

In this respect, the Examiner in the Final Rejection, at page 3, third paragraph states:

> Applicants also argue that the Gleichenhagen invention lacks plasticizer. The Examiner reiterates that the reference teaches that it is well known in the art to employ [a] plasticizers in [a] wound-dressing sprayable composition.

The Examiner at page 3, third paragraph of the Advisory Action, also repeats this same position:

> Applicants' argument that Gleichenhagen teaches a composition that does not require a plasticizer is unpersuasive. There seems to be no particular teaching against adding the additive that is conventionally used in the art, as indicated in both Gleichenhagen and Tipton.

The Examiner appears to be referring to the introduction to Gleichenhagen et al, at col. 1, lines 24-64, which discusses the prior art sprayable bandage formulations known. It should be noted that Gleichenhagen, col. 1 lines 24-30 states:

> Such polymer solutions [that is prior art solutions], which form a film over the injured site that closes the wound area … can have quite varying compositions. ……. Such solutions are preferably packaged in aerosol containers together with a propellant and find commercial use in this way.

Thus, it is submitted that the Examiner has erred in this conclusion drawn in respect to the use of plasticizers in the invention of Gleichenhagen et al. Gleichenhagen et al clearly teaches away from the use of a plasticizer.

It is also clear from the above that the disclosure of Gleichenhagen et al relates to aerosol formulations, as the

concentrated polymer solutions are charged into an aerosol container together with a propellant in the form of a liquefied propellant gas, such as a halogen hydrocarbon and other solvents (column 6, lines 36-40). This is a further distinction from the presently claimed invention which is NOT an aerosol.

Furthermore, Appellant submits that the discussion of the prior art with respect to the use of plasticizers in Gleichenhagen et al is in relation to aerosol formulations. These formulations are packaged in canisters, which in addition to the bandage composition also include an "inert" liquefied propellant. This propellant pressurizes the canister so that when the valve on the canister is actuated the bandage formulation is forced out of the canister and aerosolized.

In contrast, the presently claimed invention relates to non-aerosol formulations, that is formulations which do not employ a propellant to propel the formulation out of the container it is stored in.

Non-aerosol formulations of Appellant's invention have different considerations compared to those of aerosol formulations of Gleichenhagen et al and one of the challenges in preparing an non-aerosol product is preparing a formulation, which in use, does not block the valve of the container and still provides a high quality wound bandage.

Furthermore, non-aerosol formulations of the presently claimed invention are advantageous in that they avoid patient discomfort resulting from having a cold propellant sprayed onto them, which may be painful if, for example, the wound being dressed is open.

Additionally, it should be noted that all propellants, even hydrocarbon propellants are thought to have a detrimental effect on the environment, and therefore formulations such as those presently claimed are also advantageous because they avoid the use of propellants.

The characteristics required for a non-aerosol formulation are different to those required for an aerosol formulation, such as taught in Gleichenhagen et al. Thus, it is submitted that a teaching in the prior art in relation to aerosol formulations is not directly applicable to the claimed non-aerosol formulations.

Gleichenhagen et al, col. 2, lines 18-24 continues:

> A large number of characteristics are required of a film-forming polymer which can be sprayed in solution form, ..., and which is to produce a high quality wound bandage. These characteristics can in part be combined only with difficulty, since some of them normally exclude one another.

It can be seen from the above quote that finding a combination of components to give the desired characteristic is not straightforward because of the complex inter-relationship between the components.

An additional level of complexity to the formulation is added when the method of delivery is considered and particularly the interaction between the device which delivers the formulation and the components of the formulation.

For the reasons set out above it is respectfully submitted that the Examiner has not accurately considered the teaching of Gleichenhagen et al and has erred in the conclusion that the presently claimed invention is obvious over Gleichenhagen et al

in view of Tipton et al or Modak et al. That is, the Examiner's rejection can only be made in hindsight, which is legally improper.

Moreover, as to Claims 35-36, Gleichenhagen et al does not teach or suggest the specific plasticizer claimed therein (also recited in Claim 33), much less the specific combination of components recited in Claims 35-36.

2. Tipton et al

Tipton et al relates to two-part compositions, where a thermoplastic polymer, with an optional bioactive agent in an organic solvent, is applied to the skin, then contracted with an aqueous base fluid to coagulate or solidify the film onto the human or animal tissue (see column 3, line 57, to column 4, line 9 thereof). The thermoplastic polymer of Tipton et al is substantially insoluble in the aqueous fluid, giving rise to coagulation and film formation. Appellant submits this is entirely different from the present invention which is a one-step composition.

The mechanism for delivery of the water-soluble compound (e.g., peptide) in the present invention is taught at page 6, lines 19-34 of the present specification. There is no water in the film of the present invention (in view of the "consisting essentially of" language), in distinct contrast to Tipton et al. However, when the film of the present invention comes into contact with the moisture of the skin, the water-soluble material can leach out of the film.

Thus, Tipton et al teaches compositions and methods which are very different from those claimed in the instant invention and Gleichenhagen et al.

The biologically active agent of Tipton et al, such as tolfanate described at column 9 thereof is included in the first part of the composition of Tipton et al, which comprises the biodegradable, substantially water-insoluble thermoplastic polymer in a pharmaceutically acceptable solvent. This composition is applied to the skin, and contacted with a liquid composition with an aqueous-based fluid to coagulate or solidify the film onto human or animal tissue. Appellant submits this two-part composition clearly teaches away from Appellant's invention, which is not aqueous based and would not have been combined by one skilled in the art with Gleichenhagen et al to achieve the present invention.

Tipton et al teaches a biodegradable microporous film dressing, preferably having a two layered structure (see Figure 2 and col. 2, line 62) comprising a biodegradable/bio-erodible thermoplastic polymer such as described on column 5, lines 25-35, which include:

> ...polylactides, polyglycolides, polycaprolactones, polyanhydrides, polyamides, polyurethanes, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyorthocarbonates, polyphosphazenes, polyhydroxybutyrates, polyhydroxyvalerates, polyalkylene oxalates, polyalkylene succinates, poly(malic acid), poly(amino acids), poly(methyl vinyl ether), poly(maleic anhydride), chitin, chitosan and copolymers, terpolymers, or combinations or mixtures therein.

An essential element of the invention described in Tipton et al is the biodegradable polymer. This is a subclass of polymers, as a large number of known polymers are not considered to be biodegradable.

It appears from Tipton et al that the biodegradable polymers' solubility in organic solvents can be improved by employing a glycolide. However, Tipton et al does not directly and unambiguously describe these glycolides as biodegradable polymers.

The formulations of Tipton et al may also include a pore-forming agent (col. 7, lines 34 and 35). These pore-forming agents include (col. 7, line 64 to col. 8, line 1):

> …for example, sugars such as sucrose and dextrose, salts such as sodium chloride and sodium carbonate, and polymers such as hydroxylpropylcellulose, carboxymethylcellulose, polyethylene glycol and polyvinylpyrrolidone.

Given the discussion above and in the context of the entire specification, one skilled in the art would understand that the pore-forming agents in Tipton et al are distinct from biodegradable polymers.

Tipton et al does not suggest in the general description or the examples thereof that these pore-forming agents can be employed by preparing sprayable dressings in the absence of the biodegradable polymers.

The presently claimed invention relates to a non-aerosol sprayable skin bandage, which contains:

> 1% to 50% w/w of at least one substantially water insoluble film-forming agent selected from the group

> consisting of acrylic acid, polyacrylic acid, polybutylmethacrylate, polymethacrylic acid, ascorbyl palmitate, carbomer, cellulose acetate phthalate, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, ethyl cellulose, hydroxpropyl methlycellulose phthalate, hypomellose phthalate, crospovidone, cetyl alcohol, poloaxmer, polyethylene glycol, polyvinyl acetate, polyvinyl acetate phthalate, polyvinyl alcohol, and povidone.

Appellant submits that none of these film-forming agents are biodegradable polymers.

It is also submitted that Tipton et al does not teach formulations, which do not contain a biodegradable polymer, as in the present invention (in view of the "consisting essentially of" language). Further, Tipton et al does not provide a motivation for one skilled person to exclude the biodegradable polymer employed in the formulations described therein.

Moreover, as to Claims 35-36 Tipton et al does not teach or suggest the specific plasticizer claimed therein (also recited in Claim 33), much less the specific combination of components recited in Claims 35-36.

3. Modak et al

Modak et al describes compositions of zinc gluconate gel as an irritant-inactivating agent.

The compositions therein appear primarily to be gels but may be a cream, lotion, spray or film-forming base.

The composition may be applied to a physical barrier, such as a wound dressing or a glove or condom (col. 11, lines 25-26; and col. 12, lines 3-4).

It is clear from reading the specification of Modak et al that the composition thereof even when in the form of a gel, is not a sprayable bandage/patch of the type of the presently claimed invention. Rather, it is to be used in conjunction with traditional dressings, such as lint and gauze, which acts as the physical barrier. In fact, the invention of Modak et al can more accurately be described as a "barrier cream" to prevent the irritants making contact with the skin. In one embodiment, the composition thereof is spermicidal.

Moreover, as to Claims 35-36, Modak et al does not teach or suggest the specific plasticizer claimed therein (also recited in Claim 33), much less the specific combination of components as recited in Claims 35-36.

4. Incompatible Art

As discussed already Gleichenhagen et al relates to specific co-polymers particularly using acrylic acid and methacrylic acids. These co-polymers obviate the need to use a plasticizer. These polymers are not biodegradable polymers.

Tipton et al in contrast relates to a two-part formulation using a biodegradable polymer and water, which may employ a plasticizer.

It is clear that these teaching are completely incompatible as the polymer elements are so fundamentally different. These references would not be combined by one skilled in the art to provide a teaching that the co-polymers of Gleichenhagen et al can be used with the plasticizer of Tipton et al, much less in the absence of a biodegradable polymer.

Thus, the presently claimed invention cannot be considered obvious over the combined teachings of Gleichenhagen et al and Tipton et al.

Modak et al is also incompatible with the teaching of Gleichenhagen et al, particularly because it relates to completely different subject-matter and addresses a different problem, namely preventing irritants from coming into contact with the skin. In contrast, Gleichenhagen et al addresses the problem of providing a sprayable bandage, with the required properties of flexibility etc, without plasticizers which may be toxic and irritating to skin.

A determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based upon factual evidence. The factual inquiries on which this conclusion is based are those defined in *Graham v. John Deere, Co*, 383 U.S. 1 (1966), and more recently restated in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). These factual inquiries are:

(1) the scope and content of the prior art;

(2) the differences between the invention of the prior art; and

(3) the level of ordinary skill in the art.

Appellant respectfully submits that the Examiner's technical considerations of the scope and content of the cited prior art (Gleichenhagen et al and/or Tipton et al and/or Modak et al), has failed to properly consider the differences between the prior art and the claimed invention.

Gleichenhagen et al relates to co-polymers particularly using acrylic acid and methacrylic acids. These co-polymers obviate the need to use a plasticizer and as discussed in detail above, does not describe or suggest the presently claimed invention. Thus, the disclosure in Gleichenhagen et al does not render the presently claimed invention obvious.

Tipton et al in contrast relates to a formulation using a biodegradable polymer and water, which may employ a plasticizer and does not describe the combination of features of the presently claimed invention, nor provide a motivation for a skilled person to modify the formulations of Gleichenhagen et al to provide the presently claimed invention. Thus, the claimed invention cannot be considered to be obvious after consideration of Tipton et al.

Furthermore, given the discussion above in relation to the incompatibility of these references, one skilled in the art would not combine the teaching thereof. Furthermore, even if combined these references do not provide or suggest the presently claimed invention.

Additionally, one skilled in the art would not look to the irrelevant teachings of Modak et al in a different field (gels) to achieve the presently claimed invention (non-aerosol sprayable composition).

Thus, it is respectfully submitted that the Examiner has erred in concluding that the presently claimed invention is obvious over the combined teaching of Gleichenhagen et al in view of Tipton et al and/or Modak et al.

In this respect, Appellant also considers that the Examiner's comment on page 4, first full paragraph of the Advisory Action that:

> [E]xaminer's proposed rejection does not require a motivation for a routineer to combine the different types of the film forming polymers or substitute one for the other.

is in error in view of the clear opposing nature of the teachings of the cited references.

The Examiner states in the Final Rejection, page 4, first paragraph:

> The Tipton reference was cited to show that it is well known to add anti-fungal active agent in a wound-dressing sprayable composition.

The Examiner is apparently using this alleged general knowledge to combine incompatible documents in an improper way. Furthermore, even if tolnaflate from Tipton et al was combined with Gleichenhagen et al, such would not provide the presently claimed invention, rather it would provide a composition comprising a co-polymer using acrylic acid and methacrylic acids absent a plasticizer and incorporating the antifungal tolnaflate. This would not fall within the scope of the presently claimed invention, and therefore cannot be considered to render the same obvious.

Furthermore, Gleichenhagen et al states at col. 6, line 68 to col. 7, line 1:

> The solution can additionally contain blood coagulating, antiseptic, or bacteriostatic substances

> and/or aromatic materials (odorants) that are non-irritating to the skin.

In this respect it is noted that these additional components do not include an antifungal agent, which is the class of drugs to which tolnaflate belongs. This is an additional reason why the combination of Gleichenhagen et al with Tipton et al is incompatible.

The Examiner comments on the incompatibility of Gleichenhagen et al and Tipton et al, in saying, on page 3, third full paragraph of the Advisory Action that:

> ...Gleichenhagen and Tipton are both in the field of the applicants' endeavor and directly pertinent to the problem with which the applicant was concerned....

Appellant submits that the Examiner is in error in the assertion that simply because two references are in the same technical field the teaching of the same can be combined regardless of their incompatibility.

In fact, Appellant submits that such does not obviate the requirement to show why one skilled in the art would combine the documents.

Appellant submits that the improper conclusion in relation to obviousness of the presently claimed invention is based on hindsight reasoning employed by the Examiner.

Page 4, last paragraph of the Advisory Action and page 2, last paragraph of the Final Rejection state:

> [The determination] on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of the ordinary

> skill at the time the claimed invention was made and does not include knowledge gleamed only from the Applicant's disclosure such a reconstruction is proper.

Appellant submits that, the Examiner's inappropriate emphasis on what was believed to be generally known combined with a complete disregard for what the cited references actually say, results from the Examiner using knowledge of the invention when reading the cited references, i.e., a hindsight approach, which is legally improper.

This inappropriate approach has caused the Examiner to combine the cited references in a way that would not have been done by one skilled in the art before the earliest priority date of the claimed invention, and to conclude that the claimed invention is obvious. This error has been perpetuated by the failure of the Examiner to cite any motivation for a skilled person to combine the cited references.

Appellant believes that an objective review of the cited references with common knowledge of the skilled person before the priority date of the claimed invention, leads one to the conclusion that the presently claimed invention is not obvious.

VIII. CONCLUSION

Gleichenhagen et al is a reference over 25 years old, which teaches a specific polymer film for the application to wounds. It deals with the problems of aerosol spray-on bandages, not to claim non-aerosol composition.

Appellant submits that the Examiner has technically mis-characterized the teaching of Gleichenhagen et al.

Furthermore, Appellant believes that the Examiner has used a legally improper hindsight approach to combine Gleichenhagen et al and/or Tipton et al and/or Modak et al.

Appellant believes that given all of the above, the presently claimed invention is not obvious over the cited documents either individually or in combination.

Favourable reconsideration is respectfully requested.

The present Brief on Appeal is being filed in triplicate. A check, for the statutory filing fee, under 37 C.F.R. §1.192(a) and 1.17(c), is being filed simultaneously herewith.

However, the U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees (except for the Issue Fee and the Publication Fee) to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Gordon Kit
Registration No. 30,764

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: May 10, 2004

APPENDIX

CLAIMS 22-38 ON APPEAL:

Claim 22. A non-aerosol sprayable skin patch composition consisting essentially of:

(a) 0.01% to 10% w/w of at least one water-soluble physiologically active ingredient;

(b) 1% to 50% w/w of at least one substantially water insoluble film forming agent selected from the group consisting of acrylic acid, polyacrylic acid, polybutylmethacrylate, polymethacrylic acid, ascorbyl palmitate, carbomer, cellulose acetate phthalate, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, ethyl cellulose, hydroxypropyl methlycellulose phthalate, hypomellose phthalate, crospovidone, cetyl alcohol, poloaxmer, polyethylene glycol, polyvinyl acetate, polyvinyl acetate phthalate, polyvinyl alcohol, and povidone;

(c) 0.1% to 20% w/w of at least one film plasticiser agent; and

(d) 30% to 90% w/w of at least one volatile organic solvent,

wherein said composition forms a flexible, porous and physiologically compatible skin patch when sprayed onto skin and is allowed to dry, wherein said patch disintegrates progressively over a 24-48 hour time period.

Claim 23. The composition according to Claim 22, wherein said at least one physiologically active ingredient is an antimicrobial agent and/or an antifungal agent.

Claim 24. The composition according to Claim 23, wherein the antimicrobial agent is a quaternary ammonium compound.

Claim 25. The composition according to Claim 24, wherein said quaternary ammonium compound is selected from the group consisting of cetrimide, alkylaryltrialkylammonium chloride, alkylaryltrimethylammonium chloride, amantanium bromide, benzalkonium chloride, benzethonium chloride, benzododecinium bromide, cetalkonium chloride, cethexonium bromide, centrimonium bromine, and cetyldimethylethylammonium bromide.

Claim 26. The composition according to Claim 25, wherein said quaternary ammonium compound is cetrimide.

Claim 27. The composition according to Claim 23, wherein said water-soluble compound is a mixture of a water-soluble antimicrobial agent and a water-soluble antifungal agent.

Claim 28. The compound according to Claim 27, wherein said antimicrobial agent is a quaternary ammonium compound and said antifungal agent is selected from the group consisting of chlorbutanol, phenol, salicylic acids, arisoran, amoralfine, amphotericin, bifonazole, butoconazole nitrate, chlormidazole, clotrimazole, croconazole, econazole, enilconazole, fenticonazole, fluconazole, flutrimazole, isoconazole, itraconazole, ketoconazole, lanoconazole, miconazole, omoconazole, saperconazole, sertaconazole, sulconazole, terconazole, tioconazole, benzoyl disulphide, bromochlorosalicylanilide, buclosamide, butenafine, candicidicaprylic acid, chlorphenesin, ciclopirox olamine, cilofungin, fenticlor, flucytosine, criseofulvin, hachimycin, haloprogin, hamycin, hydroxystilbamidine, isethionate, loflucarban, mepartricin, natamycin, nifuroxime, p-nitrophenol, nystatin, pentamycin,

propionic acid, protiofate, pyrrolnitrin, sulbentine, terbinafine, tolciclate, tolnaftate, triacetin, and undecenoic acid.

Claim 29. The compound according to Claim 28, wherein said antifungal agent is chlorbutanol.

Claim 30. The composition according to Claim 22, wherein said at least one physiologically active ingredient is selected from the group consisting of an antiseptic, an antiparasitic, a nicotine, a cortico steroid, a pain relieving agent, a cardiac dilater, a cardiac stimulant, an antihistamine, an anti-inflammatory, an anti blood clotting agent, a growth hormone, a sex hormone, a drug commonly used for diseases in the alimentary system, central nervous system, musculoskeletal system, genitourinary system allergy or immune system, and a biologically active peptide or protein.

Claim 31. The composition according to Claim 30, wherein said at least one physiologically active ingredient is triclosan.

Claim 32. The composition according to Claim 22, wherein the film forming agent is selected from the group consisting of polymethacrylic acid, polybutyl methacrylate and polyacrylic acid.

Claim 33. The composition according to Claim 22, wherein said film plasticiser agent is polybutylphthalate.

Claim 34. The composition according to Claim 22, wherein said organic solvent is selected from the group consisting of isopropanol, acetone and ethylacetate.

Claim 35. A non-aerosol sprayable skin patch composition consisting essentially of:

(a) 0.01% to 10% w/w of at least one water-soluble physiologically active ingredient;

(b) 1% to 50% w/w of polymethacrylic acid;

(c) 0.1% to 20% w/w of polybutylphthalate;

(d) 0% to 90% w/w of isopropanol;

(e) 0% to 90% w/w of acetone; and

(f) ethylacetate up to 100% w/w,

wherein said composition forms a flexible, porous and physiologically compatible skin patch when sprayed onto skin and is allowed to dry, and wherein said patch disintegrates progressively over a 24-48 hour time period.

Claim 36. The composition according to Claim 35, consisting essentially of:

(a) 0.05% w/w of cetrimide,

(b) 0.07% w/w of triclosan,

(c) 0.6% w/w of chlorbutanol,

(d) 10% w/w of polymethacrylic acid,

(e) 1.2% w/w of polybutylphthalate,

(f) 4% w/w of isopropanol,

(g) 24% w/w of acetone, and

(h) ethylacetate up to 100% w/w.

Claim 37. A method of improving wound healing or administering a physiologically active ingredient to a patient comprising spraying on to a wound or on to skin of a patient in need thereof, an effective amount of a composition according to Claim 22.

Claim 38. A method for the treatment of skin wounds, fungal infections, eczema, bacterial infections in or on the skin and/or associated with skin wounds, athlete's foot, skin ulceration, burns, scalds, insect bites, allergic skin diseases, psoriasis, itching and pain, which comprises spraying on to skin in need of such treatment a composition according to Claim 22.